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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,181	02/26/2004	Charles R. Mooney	ECC-5062CIP2DIV	6985

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EXAMINER	
VU, QUYNH-NHU HOANG	

ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,181	MOONEY ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *6-8,13,14,17,18 and 21-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9-12,15,16,19,20 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 05/18/10 have been entered.

Claims 1-5, 9-12, 1516, 19-20 and 27 are present for examination.

Claims 6-8, 13-14, 17-18, 21-26 are withdrawn.

Drawings

The drawings 43a-b (Elected Species) are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation: "**the introducer including a hemostasis valve in a fixed location within the hub…**"; the limitation: "**a catheter including a catheter valve**" of claims 1, 15 and 27; and the limitation "**wherein both the at least one lumen in the catheter tube and the side arm lumen empty into, and are in fluid communication with, the access tube lumen**" of claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 15 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1, 15 and 27, nowhere in the specification described in Elected Species Figs. 43a-b that: the introducer 762 having a hemostasis valve. The catheter 764 including a junction housing 770, but does not show a catheter valve. Is the catheter 764 of Elected Species (Figs. 43a-b) same as catheter 10 in Fig. 1?

Furthermore, no where in the Specification discloses the limitation that: wherein both the at least one lumen in the catheter tube and the side arm lumen empty into, and are in fluid communication with, the access tube lumen, as described in claims 1 and 15.

The dependent claims 2-5, 9-12, 16, 19-20 are also rejected, as being of improper dependent form for failing to further limit the subject matter of independent claims 1, 15 and 27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 9-12, 15-20, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishijima et al. (US 5,092,846) in view of Constantz (US 6,712,798).

Regarding claim 1-2, 10-12, As best as understood, Nishijima discloses a multiple lumen access device for medical uses comprising:

an infusion introducer having an access tube 5 with a proximal end and a distal end for introduction into the body, the introducer including a hub 2 connected to the proximal end of the access tube and a hemostasis valve 3 in a fixed location within the hub that provides a seal against blood flow around medical implements that are introduced and withdrawn to and from the body through an access tube lumen, the introducer further including a side arm tube 8 with a side arm lumen connected in fluid communication with an opening 7 defined in the access tube distal the hemostasis valve 3; wherein a medical solution can/(or capable of) flow/flowing through the side arm lumen through the opening 7 and into the access tube lumen to mix with the blood flow immediately distal the hemostasis valve 3; wherein a medical solution can flow through the side arm lumen through the opening and into the access tube lumen to mix with the blood flow distal the hemostasis valve;

a catheter including a catheter tube 12 and a junction housing (portion of 9 and 10, Fig. 1B) on a proximal end of the catheter tube, the junction housing having a proximal end and a distal end and including a main channel 10; wherein the main channel 10 being in fluid communication with at least one lumen defined in the catheter tube12;

and a multi-function adapter 14 having a first unit 16 and a complementary second unit 17 for coupling the catheter to the hub of the infusion introducer such that the catheter tube 12 passes through the hemostasis valve 3 into the access tube lumen; the catheter tube 12 or 6 having opening at the distal portion (Fig. 1C), therefore, at least one lumen in the catheter tube 6 or 12 is in fluid communication with the access tube lumen 5; the side arm lumen 8 is inherently in fluid communication with the access tube lumen 5;

the first unit 16 being attached to the junction housing, and the second unit 16 being fixedly attached to the hub 2, wherein the first unit 16 may be removably connected to the second unit 17.

Nishijima does not disclose a catheter valve being supported by the junction housing and configured to seal access to the at least one lumen defined in the catheter tube.

Constantz discloses a multilumen catheters device comprising: an infusion introducer 10 (Figs. 1A and 4) including a hub 16; a hemostasis valve (touhy-borst valve, col. 4, lines 35-44); a catheter 20 or 30 (Figs. 2A, 3A and 4) including a catheter tube; a catheter valve at a central port 23b or 33b (col. 4,

lines 35-44); wherein the catheter valve being supported by the junction/manifold housing 28 (Fig. 2A), 38 (Fig. 3A) and configured to seal access to the at least one lumen defined in the catheter tube.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Nishijima with a catheter valve, as taught by Constantz, in order to produce a sealed relationship with the tubular element/medical implement.

Regarding claim 3, Constantz further discloses the junction housing 28, 38 includes an auxiliary channel 27 (Fig. 2B); 39, 41 (Fig. 3A) separate from the main channel; and the catheter tubes includes multiple lumens. The limitation: the catheter tube includes multiple lumens, one each in fluid communication with the main channel and the auxiliary channel, respectively.

Regarding claims 4, 9, the claimed invention requires that at least one channel on the first unit and a complementary outwardly extending lug on the second unit for engaging the channel. While, the location of first and second unit is opposite with the claimed invention such as: the first unit comprises outwardly extending lugs 16; and the second unit comprises a channel 17. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide opposite location as described in claim 4, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70.*

Regarding claim 5, Nishijima in view of Constantz discloses the claimed invention except for that one of the unit of adapter comprises L-shaped channel. It would have been an obvious matter of design choice to provide the channel in different shaped, since it appears that the invention provides the adapter would perform equally well with the adapted of the Nishijima such as the channel in one unit and a complementary outwardly extending lug on the other unit for the same purpose of engaging the channel or two parts together.

Regarding claims 15-16, 19-20 and 27, similar to the rejection of claims 1-5 and 11-12 above.

Response to Arguments

Applicant's arguments with respect to claims 1-5, 9-12, 15-16, 19-20 and 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/
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